IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

[UNDER SEAL],

Relator Plaintiffs,

SEALED COMPLAINT

v.

[UNDER SEAL],

Defendants.

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2) & (3)

JURY TRIAL DEMANDED

SEALED

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

United States of America
and the Commonwealth of Virginia
***ex rel.* Erin Craig,**

Plaintiffs,

FILED UNDER SEAL

vs.
Scott Saffold, MD
Chesapeake Bay ENT, P.C.

Pursuant to
31 U.S.C. § 3730(b)(2) & (3)

Defendants.

Jury Trial Demanded

COMPLAINT

1. *Qui tam* Plaintiff Erin Craig (Relator), through her attorneys, brings this Complaint on behalf of the United States, and on her own behalf, pursuant to the federal False Claims Act, 31 U.S.C. § 3730 *et seq*.

2. Ms. Craig alleges that Dr. Saffold claims reimbursement for claiming unnecessary medical procedures:

- Diagnostic endoscopy of the sphenoid sinus: A dangerous and complex diagnostic that involves puncturing patients' facial bones; and
- Balloon sinuplasty: Using balloons to expand patients' sinuses by fracturing small bones surrounding the sinus cavities.

I. Jurisdiction, Venue, and Parties

3. This Court has jurisdiction under 31 U.S.C. § 3732 and 28 U.S.C. § 1345. State law claim jurisdiction arises under 31 U.S.C. § 3732(b) (jurisdiction over state claims arising from the same transaction or occurrence as an action under the federal FCA), and 28 U.S.C. § 1367(a) (supplemental jurisdiction).

4. This Court has personal jurisdiction over Defendants because Defendants transact business and can be found in this district, and committed acts within this district that violate 31 U.S.C. § 3729 and 31 U.S.C. § 3732(a).

5. Upon information and belief, no jurisdictional bars apply to this action. 31 U.S.C. § 3730(e); Va. Code Ann. § 8.01-216.3.

6. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §1391(b) and (c) because Defendant resides and/or transacts business in this district and has committed acts within this district that violate 31 U.S.C. § 3729. Section 3732(a) further provides for nationwide service of process.

7. Relator has complied with all procedural requirements of 31 U.S.C. §3730(b)(2).

8. **Relator Erin Craig,** B.A. (Mathematics), M.S. (Data Science), works as a Data Scientist and is involved with using electronic health records to improve healthcare and hospital care. Her work investigating Medicare fraud and otolaryngology frauds has exposed her to the information about the medical procedures discussed below.

9. With respect to allegations made upon information and belief, Ms. Craig has, based upon her knowledge, data, and experience, a reasoned factual basis to make the allegations but lacks complete details of them. While Ms. Craig has significant evidence of the fraud alleged herein (the details of which follow), much of the documentary evidence necessary to prove the allegations in this Complaint is in the possession of the Defendants, the United States, or the Commonwealth of Virginia.

10. **Defendant Scott Saffold**, MD, NPI 1801863162 , practices medicine in Belhaven and Virginia Beach, Virginia. He is Board Certified in Otolaryngology.

11. Defendant Saffold enrolled in the Medicare Program and it is paid in excess of a $600,000 dollars per year in Medicare Part B payments.

12. **Defendant Chesapeake Bay ENT, P.C.** is an active Virginia Corporation headquartered in Virginia Beach, Virginia, and does business in Belhaven, Franklin, Virginia Beach, Suffolk, and Churchland, Virginia.

13. On information and belief, one or both Defendants agreed to comply with Virginia Medicaid program.

II. The False Claims Acts, Medicare and Medicaid Acts

A. False Claims Acts

14. The Federal False Claims Act prohibits the submission of false or fraudulent claims and false statements so as to obtain or keep federal money. It provides, in pertinent part:

> (1) In general.— Subject to paragraph (2), any person who—
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> * * *
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . ., plus 3

> times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

15. Under the False Claims Act, a private person may sue in federal district court for him/herself and for the United States and may share in any recovery. 31 U.S.C. § 3730(b). That private person is a *relator*, and the action that the relator brings is called a *qui tam* action.

16. Under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted from $ 5,500 to $ 11,000 for violations occurring on or after September 29, 1999. For violations that occurred after November 1, 2015, Department of Justice (DOJ) announced increased penalties to between $10,781 and $21,562 per fraudulent claim.[1]

17. The Commonwealth of Virginia patterned the Virginia Fraud Against Taxpayers Act on the federal statutory scheme. The requirements for state liability are substantially the same as for federal liability. Va. Code Ann. Art 19.1, § 8.01-216.1 *et seq*.

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[1] https://www.federalregister.gov/documents/2017/02/03/2017-01306/civil-monetary-penalties-inflation-adjustment-for-2017

B. Medicare and Medicaid

18. Medicare, enacted in 1965 under Title XVIII of the Social Security Act, is a third-party reimbursement program that underwrites medical expenses of the elderly and the disabled. 42 U.S.C.§§ 1395 *et seq*. Medicare reimbursements are paid from the federal Supplementary Medical Insurance Trust Fund.

19. Medicare Part B generally covers physician services, including medical and surgical treatment and outpatient treatment and diagnosis. Part B, 42 U.S.C. §§ 1395j *et seq*.; 42 U.S.C. §1395l (payment of benefits). The Medicare claims in this case primarily arise under Medicare Part B.

20. Medicaid is a medical assistance program for indigent and other needy people that is financed by joint federal and state funding and is administered by the states according to federal regulations, oversight, and enforcement. 42 U.S.C. §§ 1396 *et seq*. Each state implements its version of Medicaid according to a State Plan approved by HHS. Within broad federal regulatory and policy guidelines (*see* 42 C.F.R. § 430 *et seq*., and CMS publications), the states determine who is Medicaid-eligible, what services are covered, and how much to reimburse healthcare providers. The states, through intermediaries, also receive healthcare provider claims for program reimbursements, evaluate those claims,

make payments to healthcare providers, and present the claims to HHS/CMS for reimbursement of the federal government's share.

21. Physicians must enroll in the Medicare and Medicaid programs to be eligible to receive payment for covered services provided to program beneficiaries. 42 C.F.R. § 424.505.

22. Virginia's Department of Medicaid Assistance Services ("DMAS") administers the state's Medicaid program. Physicians must enroll in the state's Medicaid program to be eligible to receive Medicaid payments.

23. CMS requires that all claims for physician services be submitted on a form CMS-1500 (Health Insurance Claim Form) ("Form 1500") or its electronic equivalent. 42 C.F.R. 424.32 (Basic requirements for all claims).

24. At all times relevant to this action, Defendants submitted, or caused to be submitted, the electronic equivalent of Form 1500 to CMS and to Virginia's DMAS for reimbursement for services.

25. Form 1500 requires the submitting healthcare provider to include various fields of information prior to reimbursement, including: the date(s) of service; a code for the service(s) provided known as a "Current Procedural Terminology Code" or "CPT Code"); and the rendering healthcare provider's national identification number ("National Provider Identifier" or "NPI") and signature.

26. According to Form 1500's instructions, a provider's signature certifies "that services shown on [the Form 1500] were medically indicated and necessary for the health of the patient and were personally furnished by [the provider] or were furnished incident to [his/her] professional service by [his/her] employee under [his/her] immediate personal supervision."

27. Providers, such as Defendants, submit claims to Medicare by transmitting them to a private carrier or a Medicare Administrative Contractor ("MAC"), which processes the claims on behalf of HHS/CMS.

28. All healthcare providers that submit claims electronically to CMS or to CMS MACs, must certify in their application that they "will submit claims that are accurate, complete, and truthful," and must acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See* Medicare Claims Processing Manual, § 30.2.A.

29. Medicare permits reimbursement only for medical treatments which are "reasonable and necessary for the diagnosis and treatment of illness or injury . . . ."

42 U.S.C. § 1395y(a)(1)(A). *See also* 42 C.F.R. § 411.15(k)(1). Although the Secretary may issue National Coverage Determinations to define what services are considered reasonable and necessary, none has been issued for balloon sinuplasty. 42 U.S.C. § 1395ff(f)(1)(B). If there is no applicable national coverage determination, a Medicare contractor may issue a "local coverage determination" stating whether an item or service is covered within that contractor's jurisdiction. Id. § 1395ff(f)(2)(B). Where there is no applicable national or local coverage determination, Medicare contractors "make individual claim determinations . . . based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). Nonetheless, procedures may be considered unreasonable or unnecessary even without a national coverage determination.

30. Courts have looked to the CMS Medicare Program Integrity Manual, and its elucidation of what is "reasonable and necessary." It includes at § 13.3 among these requirements, that the service is:

- Safe and effective;
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- One that meets, but does not exceed, the patient's medical need; and

- At least as beneficial as an existing and available medically appropriate alternative.

31. Additionally, § 13.7.1 governs "Evidence Supporting LCDs." While § 13.3 does not specifically link to § 13.7.1, it looks to general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

- Scientific data or research studies published in peer-reviewed medical journals;
- Consensus of expert medical opinion (i.e., recognized authorities in the field); or
- Medical opinion derived from consultations with medical associations or other health care experts.

32. In addition to medical necessity and reasonableness, healthcare providers who submit claims to the Medicaid Program must certify, among other things, that all statements in the claim are true, accurate, and complete to the best of the provider's knowledge; that no material fact has been omitted; that the provider is bound by all rules, regulations, policies, standards, fee codes and procedures.

33. When submitting a claim for reimbursement, the claimant must provide documentation that supports the claim. Appropriate documentation typically involves correctly coding certain services to enable the Government to reimburse the healthcare provider at the proper rate.

34. "Upcoding" is an act of committing fraud by knowingly and intentionally submitting a claim under an inappropriate diagnostic or procedural code to obtain a higher rate of reimbursement. Upcoding also occurs by changing the procedure code to a code that pays a higher rate of reimbursement. Upcoding can harm patients medically and financially. Fabricated medical histories in patients' charts and medical records can forever skew diagnoses and treatment. This may cause a patient to undergo additional diagnostic exams or even cause a subsequent healthcare provider to perform a procedure that might be unnecessary were the patient viewed as lower risk. In addition, a patient may be declined or charged more for long-term care or life insurance due to these false diagnoses.

35. Under Medicare and Medicaid rules and policies, healthcare providers must contemporaneously create and maintain accurate medical records to support the providers' claims for reimbursement. See e.g., CMS MLN Matters Number: SE1022 ("Providers/suppliers should maintain a medical record for each Medicare beneficiary that is their patient. Remember that medical records must be accurately written, promptly completed, accessible, properly filed and retained.")

III. Otolaryngology Overview

36. Otolaryngology is a medical specialty focusing on the care and treatment of the ear, nose, and throat. Otolaryngologists are trained in the medical and surgical

management and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and neck. They are commonly referred to as ENT physicians. Otolaryngologists whose practices focus on patients with disorders of the nose, sinuses, and skullbase are also known as rhinologists.

37. Patients who seek assistance from otolaryngologists typically know their *symptoms*, which often relate to sinus and nasal airflow and drainage, and facial pain. Similar to other physicians, otolaryngologists ask their patients questions and can make some decisions based on patient responses. The AMA and Medicare call this "evaluation and management" (E/M) and reference it as CPT 99201 – 99215. Sometimes physicians may supervise nonphysician practitioner for E/M. Medicare Claims Manual, Ch. 12, § 30.6.4.

38. Because sinuses are hidden, patients are unfamiliar with their nasal anatomy and their E/M responses rarely allow otolaryngologists to sufficiently evaluate and diagnose these patients.

39. For these reasons, when a patient presents sinus-related symptoms, otolaryngologists frequently perform a nasal endoscopy, CPT 31231, a routine diagnostic procedure that allows for visual inspection of nasal anatomy and pathways to the sinuses. Otolaryngologists typically perform this in the office,

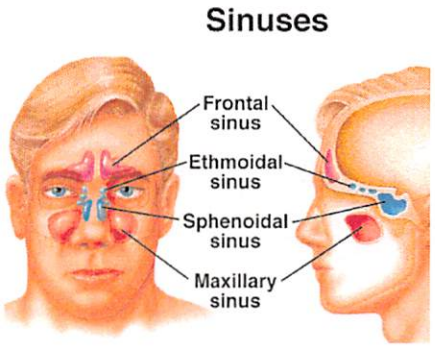
following application of a decongestant and/or local anesthetic, with an endoscope, a thin tube inserted through a nostril and into a patient's nasal airways.

40. Another increasingly common diagnostic available to otolaryngologists is a CT scan, such as CPT 70486.

IV. False Claims for CPT 31235—Puncturing Patients' Facial Bones

41. Defendant files many claims for CPT 31235, a "nasal/sinus endoscopy, *diagnostic* with sphenoid sinusoscopy [via puncture of sphenoidal face or cannulation of ostium] complicated."

42. Unlike CPT 31231, which involves looking through a nostril, the CPT 31235 diagnostic requires a physician to surgically open a hole through the front wall of the sphenoidal sinus, then insert the endoscope through the "puncture" made for that diagnostic, and into a patient's sinus.



43. The American Academy of Otolaryngology—Head and Neck Surgery clarifies that the CPT 31235 diagnostic procedure *requires puncturing a hole through a patient's facial bones and into the sinus at the time of the endoscopy.*

> Reimbursement: There have been a number of member inquiries on the correct usage of CPT® codes 31233 Nasal/sinus endoscopy,

> diagnostic with maxillary sinusoscopy (via inferior meatus or canine fossa puncture) and 31235 Nasal/sinus endoscopy, diagnostic with sphenoid sinusoscopy (via puncture of sphenoidal face or cannulation of ostium). Some who perform endoscopic exams after the postoperative global period to view the interior of maxillary or sphenoid sinuses through existing surgically created patent sinusotomies are reporting 31233 or 31235 (or, perhaps both).
>
> When the physician performs endoscopic exams postoperatively (to view the interior of maxillary or sphenoid sinuses through existing surgically created patent sinusotomies), the Academy's position is that only CPT code 31231 Nasal/sinus endoscopy, diagnostic, unilateral or bilateral (separate procedure) is appropriate. Our rationale is that *CPT* codes 31233 and *31235 require a puncture or trocar cannulation*[2] prior to placing the scope into the sinus. CPT code 31231 is bilateral while the CPT codes 31233 and 31235 are unilateral. *The use of CPT* code 31233 or *31235 to report diagnostic sinus endoscopy performed via an existing and patent opening into the maxillary or sphenoid sinus is incorrect.*

http://www.entnet.org/?q=node/679 [Emphasis supplied].

44. Observing and diagnosing sinuses by puncturing a patient's facial bones (CPT 31235) risks patient harm and is rarely necessary because diagnosis can be made with a CT scan, or with an endoscope inserted through a patient's nostril (CPT 31231).[3]

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[2] A cannula is "a small tube for insertion into a body cavity, duct, or vessel." https://www.merriam-webster.com/dictionary/cannula#medicalDictionary. A trocar is "a sharp-pointed surgical instrument fitted with a cannula and used especially to insert the cannula into a body cavity as a drainage outlet." https://www.merriam-webster.com/dictionary/trocar.

[3] If a *prior* procedure left an opening, then visualization of the maxillary sinus through the pre-existing puncture is billed using CPT 31231 (not 31235).

A. CPT 31235 is dangerous.

45. The sphenoid sinus is surrounded by vital structures including the dura (outermost membrane enveloping the brain), pituitary gland, optic nerve, pterygoid canal and nerve, internal carotid artery and the cavernous sinus with its associated cranial nerves.

46. On information and belief, there is a 41% or more rate of protrusion of the internal carotid artery into the sphenoid sinus and a 30% or more rate of dehiscence of its bony covering. "Dehiscence" means lack of a bony covering, making the artery more susceptible to traumatic rupture by an instrument. Damaging this structure in an office setting would be uniformly fatal.

47. The optic nerve is on the same side as the carotid artery. Optic nerve damage causes blindness. The pituitary gland is on the other side of the sphenoid sinus, damaging it could cause massive bleeding, cerebrospinal fluid leak and/or loss of function of the pituitary gland. And the brain (dura) sits on the roof of the sinus.

48. Specialized equipment is necessary to widen the natural ostium (drainage hole) of the sphenoid sinus, and great care and training is required to know in exactly which direction the opening should be expanded so as to avoid damage to

vital structures in and around the sphenoid sinus.[4] The ability to control what may be massive bleeding from the sphenopalatine artery, coursing just below the natural ostium, is absolutely necessary.

B. CPT 31235 is rarely necessary.

49. On information and belief, the sphenoid sinus is infrequently diseased.

50. Additionally, on information and belief, sphenoid pathology, if symptoms indicate, may safely be diagnosed using CT imaging and nasal endoscopy (viewing the outside of the natural ostium to determine whether pus, polyps, etc. are emanating from the natural ostium), without instrumenting and entering the sinus.[5] CT scanning can give all of the necessary information non-invasively. Given the availability of CT scanning in Virginia, there is virtually no need to ever puncture a sinus to look into it from a diagnostic perspective.

51. It appears Dr. Saffold's patients receive CT scans. CMS reveals Medicare part B providers, including diagnostic radiologists, seen by patients in the 30 days

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[4] On information and belief, the sphenoid sinus is classically accessed with a 4 mm diameter endoscope. The orbit (hole) must be larger than the endoscope, often >7 mm (.27 in). A pencil eraser is approximately 6 mm; a collar button approximately 7 mm.

[5] "*A high index of clinical suspicion, routine office nasal endoscopy and radiological imaging are central* to making an accurate and timely diagnosis of isolated sphenoid sinus pathology." https://www.ncbi.nlm.nih.gov/pubmed/18242904/. [emphasis supplied]

before and after they see Saffold. Relator infers – but does not know – that diagnostic radiologists conducted CT scans on the shared patients.[6]

C. Dr. Saffold claims too many 31235 diagnostics, including duplicates

52. More than 10% of Dr. Saffold's diagnostic procedures are claimed under 31235.

53. Significantly, Dr. Saffold claims this procedure more than once per patient. During the three years 2014 through 2016 CMS data shows it paid for approximately 120 duplicate procedures at a cost of $38,680.

year	total payment	total procedures	total patients	duplicate procedures	$ / proc	dup pmt total
2014	32,105	100	29	71	$ 321	$ 22,795
2015	19,250	59	24	35	326	11,419
2016	9,581	30	16	14	319	4,466
	60,936			120		$ 38,680

54. The above chart likely *understates* duplicate procedures because it does not identify patients who receive a first procedure the preceding year or the following year.

[6] For example, in 2015, his patients saw in the 30 days before or after his services, radiologists: James Mosure, NPI 1295829067; William Marshal, NPI 1477533107; and Valentine Curran NPI 1568432672 (preceding only, not following). Most of these patients were shared with Dr. Mosure.

55. With respect to the medical necessity for CPT 31235 and customary rhinological practices in and around Virginia, Relator concluded:

- The lack of other otolaryngologists' claims under this code indicates no "cluster" of symptoms or diagnoses that would suggest Defendant's volume of CPT 31235 procedures are medically reasonable or necessary.
- The lack of other otolaryngologists' claims indicate it is medically unreasonable and inappropriate to routinely and invasively puncture a patient's facial bones for a routine diagnostic,
- The lack of other otolaryngologists' claims suggests it is usually medically unreasonable and inappropriate to puncture this sinus to look into it from a diagnostic perspective.

56. Relator estimates that many of Defendant's CPT 31235 claims are false.

57. Viewing Defendant's Medicare 31235 claim volume, fourth highest in the nation, and without knowing more, a layperson might conclude he is a specialist in the sphenoid sinus. However, there is no such specialty or subspecialty in this sinus, or this procedure.

58. There are certain procedures, such as new transplant techniques, in which patients might seek a particular physician for a particular procedure. Such renowned physicians might draw patients from all over the country. This is not such a procedure, and Defendant is not such a physician. No patient's awareness of their symptoms enables self diagnoses indicating the necessity for this particular procedure.

59. Similarly, the volume of this procedure also suggests the possibility of referrals from other otolaryngologists. However, Relator's investigation and analysis of the Medicare shared patient data sets has determined that Defendant's 31235 claims are not generated from other otolaryngologists' patient referrals.

V. False Claims for Balloon Sinus Dilation (Sinuplasty)

60. A balloon sinus dilation, also known as a sinuplasty, is an office-based approach to improving sinus airflow and drainage by expanding sinus pathways.[7] The doctor threads a small balloon catheter through the nostril and into the sinus cavity, inflates the balloon to enlarge the sinus opening, deflates the balloon and removes it.

61. Balloon dilations are not a panacea for all sinus problems. Patients require surgeries for sinus problems that cannot be resolved with balloon dilation. These problems include deviated septums, nasal polyps, enlarged turbinates and others. These are described below. Routine diagnostics, such as endoscopies (CPT

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[7] CPT coding depends on the sinus dilated:

- 31295 Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (*e.g.,* balloon dilation), transnasal or via canine fossa.
- 31296 Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (*e.g.,* balloon dilation).
- 31297 Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (*e.g.*, balloon dilation).

31231) and CT scans (CPT 70486), disclose these conditions. [8]

62. Even when a balloon dilation might be appropriate, surgeons cannot perform balloon dilations when a patient's nasal passages are so blocked that the surgeon cannot even insert a balloon. Some common blockages include nasal polyps, deviated septums, aerated middle turbinates (concha bullosa), and large inferior turbinates. These are described below.

A. Conditions Not Addressed with Sinuplasty

1. Deviated Septums

63. The nasal septum is the dividing wall that runs down the middle of the nose, separating the two nasal cavities, each of which ends in a nostril. Doctors sometimes straighten a crooked (deviated) nasal septum to improve breathing, or to improve visualization of the nasal interior for treatment of polyps, inflammation, tumors, or bleeding.[9]

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[8] The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) *Clinical Consensus Statement: Balloon Dilation of the Sinuses,* which ARS endorsed, was published in the AAO-HNSF journal, Otolaryngology–Head and Neck Surgery, on February 1, 2018. https://www.american-rhinologic.org/ps_balloon_ccs, see Clinical Consensus Statement: Balloon Dilation of the Sinuses, http://journals.sagepub.com/doi/full/10.1177/0194599817750086.

[9] Septoplasty corrects deformities of the partition between the two sides of the nose (the septum). Common CPT codes include:

- 30520 Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
- 30620 Septal or other intranasal dermatoplasty (does not include obtaining graft).

64. For some patients with deviated septums, a balloon dilation may be impossible because the surgeon cannot thread the balloon past the septum.

65. But even when a balloon can be inserted past a deviated septum, it may be the wrong course of treatment (medically unreasonable and unnecessary), and surgery may be required to repair the deviation.

2. Nasal Polyps

66. Nasal polyps are soft, lack sensation, and are invisible to patients.

67. On information and belief, they occur in 19% to 36% of patients with chronic rhinosinusitis. Patients rarely know they have nasal polyps so and so they do not report them during E/M interviews. For some patients, multiple polyps or a large polyp may block nasal passages and sinuses so much that a balloon cannot be inserted. Even when a balloon can be inserted, it may be the wrong course of treatment, or just an adjunct to a surgical procedure. In addition, polyps may themselves widen the opening of a sinus and cause obstruction. A balloon dilation would have no effect in that instance. Only removal of the polyp(s) would overcome the obstruction. Because balloons do not resolve issues related to polyps, surgery may still be required to remove them.

3. Enlarged Turbinates

68. Three turbinates on each side of the nose help clean and humidify air as it moves through the nose. But excessively large turbinates block the sinuses. Turbinate reduction surgery seeks to correct nasal obstruction by reducing the turbinate size and thereby decreasing airway resistance while preserving the natural function of the turbinates.

69. On information and belief, a majority of patients with chronic sinusitis will have enlarged turbinates and so will need turbinate reduction.[10]

70. While different doctors take different approaches to turbinate reduction, *balloons do not reduce turbinates.*

4. Other circumstances, and risk of patient harm

71. Other circumstances in which balloon dilation is not medically necessary include:

- Patients with extensive scarring of their sinus openings.
- Prior surgery to surgically expand sinus openings by removal of tissue
- A sinonasal tumor causing the obstruction

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[10] Common CPT codes include:
- 30140 Resect inferior turbinate
- 30802 Ablate inf turbinate submuc
- 30130 Excise inferior turbinate

72. Balloon dilation is generally safe. Under certain circumstances, however, it may pose a risk to patients. Such circumstances include when a prior surgery has altered the anatomy and exposed vital structures; or when there is unusual anatomy, such as a dehiscent carotid artery in the sphenoid sinus herniating into the sinus, thereby risking its puncture when performing a balloon dilation.

B. Defendants ignore patients' polyps, septums, and turbinates.

73. Although Dr. Saffold files many Medicare claims for balloon sinus dilations, far more than anyone in Virginia, and nationwide number three in 2016, and number four in 2015, he has not filed claims for the surgical treatment of nasal polyps, deviated septums, or enlarged turbinates.

74. Research supports that 25-30% of chronic rhinosinusitis patients (the patients who seek relief from an otolaryngologist) have symptomatic polyps. But Dr. Saffold's claims show he does not surgically treat his patients' polyps. [11]

75. With respect to the frequency of polyps that would block a balloon dilation, or that would require treatment to improve airflow and drainage, there is no data

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[11] "[Balloon dilation] can be appropriate as an adjunctive procedure to sinus surgery in patients with chronic sinusitis *without nasal polyps*." Emphasis supplied. Clinical Consensus Statement: Balloon Dilation of the Sinuses. http://journals.sagepub.com/doi/full/10.1177/0194599817750086

indicating any unique conditions in Virginia explaining Defendants' patients' absence of polyps.[12]

Similarly, there is no data showing any purported absence of deviated septums and enlarged turbinates in Virginia .

C. Defendants' Duplicate Procedures

76. Paid Medicare part B claims in 2014, 2015 and 2016 show patients who receive the procedures more than once.

year	total payment	total procedures	total patients	duplicate procedures	$ / proc	dup pmt total
2014	$ 56,233	63	39	24	893	$ 21,422
2014	106,913	62	39	23	1,724	39,661
2014	49,811	59	36	23	844	19,418
	$212,957			70		$ 80,501
2015	95,254	114	66	48	836	40,107
2015	191,286	114	65	49	1,678	82,219
2015	94,064	112	65	47	840	39,473
	$380,604			144		$161,800
2016	111,248	132	78	54	842	45,511
2016	226,356	132	78	54	1,715	92,600
2016	111,401	132	78	54	844	45,573
	$449,005			162		$183,684

77. This chart probably *understates* duplicates because it does not identify patients whose procedures overlap two years.

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12 There are geographic variations in some rhinological procedures. For example, Florida has more mold, and other areas may be especially dry during the winter. These conditions may impact patients' symptoms and treatments. But there are no conditions unique to Virginia that would impact patients' nasal anatomies, or their polyps, septums, or turbinates.

78. For each of the three balloon procedures, 31295, 31296, and 31297, which address distinct sinuses, Defendant Saffold appears to perform the set of procedures a *second* time for patients in the same year. This is unlike any other Medicare provider in the country.

79. In comparison to others' claims, Defendant's claims suggest his patients require treatments that differ wildly from national norms and from Virginia's professional norms and standards of care. This is because few patients of other physicians who claim balloon procedures (CPTs 31295, 31296, and 31297) require a second set of procedure within months of the first set.

80. While Relator knows of no studies or guidelines on repeating these procedures, the effectiveness of balloon sinuplasty is measured by the "patency rate," the likelihood that the nasal passage will remain open (a more open nasal passage correlates with greater nasal airflow). Some studies show up to a 98% patency rate after dilation.[13] In contrast, Dr. Saffold's claims reflect a near 0%

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[13] "1.3% revision" (meaning 98.7% no revision) https://www.ncbi.nlm.nih.gov/pubmed/24598043
"Outcomes out to 2 years … success is 97.5%" https://www.ncbi.nlm.nih.gov/pubmed/26228589
"Overall, BSD [balloon sinus dilation] instruments were successful in dilating 97.6% of targeted sinuses" https://www.ncbi.nlm.nih.gov/pubmed/27325205
Patency rates 90% - 98% https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3738804/
Patency 92% (for patients without polyps) https://www.ncbi.nlm.nih.gov/pubmed/25457065

patency rate. This suggests that the first set of procedures were:

- improperly performed,
- not medically reasonable, or
- not medically necessary.

D. Defendant's claims appear to be revenue-driven

81. The implicit "facility fee" built into the procedures' reimbursement makes ballooning more lucrative for Dr. Saffold than for otolaryngologists who address their patients' septums, polyps, turbinates, or other issues that require surgery. This is because Dr. Saffold need not incur the substantial expenses associated with a surgical practice, even though "non-facility" reimbursement rates take this expense into account when reimbursing his CPT 31295, 31296, and 31297 claims.

82. The difference between facility (such as a hospital) and non-facility rates reflects the implicit "practice expense" incurred by surgeons who incur substantial expenses for establishing and maintaining equipment and supplies, and for providing clinical staff.[14] For example, the facility rates, even in 2017, are far less than what CMS paid Dr. Saffold.

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[14] This is also referred to as the "practice expense." https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedcrePhysFeeSchedfctsht.pdf

CPT	2017 Facility Rate [15]	2016 Saffold Payment
31295	$168	$ 843
31296	202	1,715
31297	165	844
Aggregate	$ 535	$ 6,215

83. On information and belief, generally, surgeons must maintain level II compliance (and incur compliance costs) for anything more than a simple skin excision with minimal sedation and complete responsiveness of the patient.[16] Any combination of sedative and narcotic, as is often used in office-based surgical procedures performed by otolaryngologists (who address problems that Dr. Saffold ignores), would likely result in level II surgery overhead and expenses.[17]

84. Because Defendant does not perform the ancillary surgical procedures, he avoids the substantial expense of developing and maintaining a level II surgery practice.

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[15] https://www.cms.gov/apps/physician-fee-schedule/search/search-results.aspx?Y=1&T=0&HT=0&CT=3&H1=31295&M=5

[16] "Multiple studies have now evaluated SOD of the sinuses under local anesthetic alone" footnotes omitted. http://journals.sagepub.com/doi/full/10.1177/0194599817750086.

[17] The American Society of Anesthesiologists (ASA) defines the various levels of anesthesia (sedation) as follows:

Level 1 – Minimal sedation (anxiolysis) A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Level 2 – Moderate sedation ("Conscious Sedation") A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

VI. Relator is an Original Source and Uncovered the Fraudulent Conduct

85. The allegations or transactions herein were not publicly disclosed. Relator is an original source of the information on which their allegations are based within the meaning of the FCA and the Virginia Fraud Against Taxpayers Act. To the extent there were any qualifying public disclosures, Relator's allegations materially add to any information contained in any such public disclosures.

86. The Centers for Medicare and Medicaid Services (CMS) disclose hundreds of databases. Some are available online and others may be ordered from CMS. https://data.cms.gov/

87. CMS disclosed data through the "Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File." This data is based on information from CMS's National Claims History Standard Analytic Files. It contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population.[18]

88. Each year's PUF database contains more than 242 million entries relating to a single year's Medicare Part B claims. However, this raw data does not reveal the alleged frauds. In particular:

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[18] http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html as of October 10, 2014.

i. It does not compare providers by amounts billed, amounts paid, procedures performed, or otherwise.
ii. It does not disclose medical relationships between procedures.
iii. It does not reveal procedures *not* performed that should have been performed
iv. It does not reveal dangerous procedures for which there are less dangerous alternative approaches (such as CT scans).

89. Relator's knowledge of the relationship between the particular medical procedures and diagnostics discussed herein gives her the knowledge, skills, and experience to analyze Defendants' and others' Medicare claims data and to make the allegations in this Complaint.

90. For certain analyses Relator used professional knowledge and skills to guide the selection and aggregation of certain codes (for example 31295, 31296, 31297) for the statistical analyses of these code aggregates. Then, using these figures—which were not revealed by CMS— and based on analysis and synthesis of millions of records—applied her knowledge, skills, and experience to what the data revealed, to what it did *not* reveal.

91. Data on which Relator based her analysis also included "Shared Patient Data Sets," which CMS has released for 2009 through 2016, in 30-, 60-, 90- and 180-day intervals. This is an even more voluminous data set. For example, one

database (30 days) for a single year (2014) contained 55,779,669 records. [19]

92. Because there is nothing inherently fraudulent with performing the procedures described herein, data resulting from this analysis and synthesis support these allegations but, by itself, this data did not "disclose" the allegations herein.

VII. Counts I – III

A. Count I: Violations of 31 U.S.C. § 3729(a)(1)(A)

Plaintiff repeats and realleges ¶¶ 1- 92 above as if fully set forth herein.

93. Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval to Government Health Care Programs, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

94. The United States paid said claims and has sustained damages because of these acts by the Defendants.

B. Count II: Violations of 31 U.S.C. § 3729(a)(1)(B)

Plaintiff repeats and realleges ¶¶ 1- 92 above as if fully set forth herein.

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[19] Relator has not included this data an exhibit. The 9 million record part B file would require 27 million pages. If printed, 5,400 standard cartons. Stacked four high, and lined end to end, the cartons would stretch 6 1/2 football fields (1,969 feet). Each of the 55 million+ record shared patient data sets would require even more cartons.

95. Defendants knowingly made, used or caused to be made, or used false records or statements material to a false or fraudulent claim, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

96. The United States paid said claims and has sustained damages because of these acts by the Defendant.

C. Violations of the Virginia Fraud Against Taxpayers Act

Plaintiff repeats and realleges ¶¶ 1- 92 above as if fully set forth herein.

97. The Virginia Fraud Against Taxpayers Act imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. Va. Code Ann. § 8.01-216.3(A)(1)-(A)(2).

98. Defendants' actions, if known, would have affected Virginia's decision to pay the resulting claims.

99. Defendants' actions violated material conditions of payment under Virginia's healthcare program.

100. By virtue of the acts described above, Defendants knowingly caused to be presented false or fraudulent claims to Virginia for payment or approval. Va. Code Ann. § 8.01- 216.3(A)(1).

101. By virtue of the acts described above, Defendants knowingly caused to be

made or used false records and statements to induce Virginia to approve and pay such false and fraudulent claims. Defendants acted knowingly, as that term is used in the False Claims Acts

102. Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid claims that would not have been paid had Virginia been aware of Defendants' unlawful conduct.

103. By reason of Defendants' concerted acts, Virginia has been damaged in a substantial amount to be determined at trial.

PRAYER

WHEREFORE, *Qui Tam* Plaintiff Relator, for the United States, Virginia, and for herself, prays that judgment be entered against Defendant as follows:

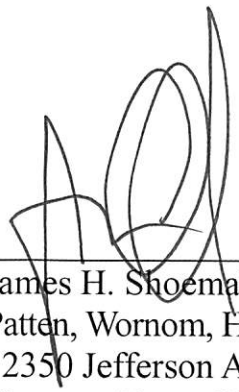
A. For each count, the amount of damages, trebled as required by law, and civil penalties up to the maximum permitted by law,

B. For the maximum *qui tam* percentage share allowed by law,

C. For attorney's fees, costs and reasonable expenses; and

D. For any and all other relief to which Plaintiffs may be entitled.

Plaintiff requests trial by jury.



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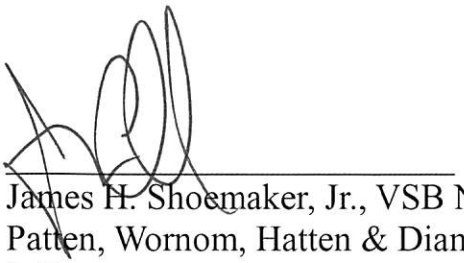
Attorneys for *Qui Tam* Plaintiff Relator

This Complaint will **not** be served on Defendants until ordered by the Court.

I HEREBY CERTIFY that the foregoing Complaint shall be mailed, postage prepaid, certified mail to:

- Jeff Sessions III, Attorney General, United States Department of Justice, c/o Sealed Document Civil Process Clerk, 10th and Constitution, Washington, D.C. 20530;
- G. Zachary Terwilliger United States Attorney, 2100 Jamieson Ave. Alexandria, VA 22314.
- Mark Herring, Office of the Attorney General, Attn: Seal Clerk, 900 East Main Street, Richmond, VA 23219.

And served via email only to Gerard Mene, Assistant United Sates Attorney, Gerard.Mene@usdoj.gov.



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